



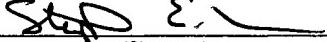
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Atty. Dkt. No. ABI1550-1
(071243-1404)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Soon-Shiong and Desai
Title: LONG TERM ADMINISTRATION
OF PHARMACOLOGICALLY
ACTIVE AGENTS
Appl. No.: 09/937,840
Filing Date: 09/26/2001
Examiner: Unknown
Art Unit: 1614

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Stephen E. Reiter, Reg. No 31,192
(Printed Name)

(Signature)
5/9/03
(Date of Deposit)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

IDS TRANSMITTAL

Sir:

Transmitted herewith for the above-identified application please find:

- (1) Information Disclosure Statement.
- (2) Completed Form PTO/SB/08.
- (3) Copies of the cited references
- (4) Postcard.

In re Application of:
Soon-Shiong and Desai
Application No.: 09/937,840
Page 2

PATENT
Atty. Dkt. No.: ABI1550-1
(071243-1404)

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date 5/9/03

By Steph E.

FOLEY & LARDNER
Customer Number: 30542



30542

PATENT TRADEMARK OFFICE

Telephone: (858) 847-6711
Facsimile: (858) 792-6773

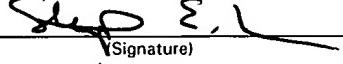


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<u>Stephen E. Reiter, Reg. No. 31,192</u> (Printed Name)	
 (Signature)	
<u>5/9/03</u> (Date of Deposit)	

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Some of the documents were cited in the International Search Report for corresponding international application PCT/US00/10849. Some of the documents were cited in the Supplementary European Search Report for corresponding European Patent Application No. EP 00 92 8296. A copy of both of the Reports is included.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed

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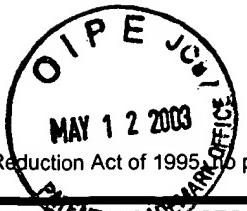
Respectfully submitted,

Date 5/9/03

By Steph E. L.

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Attorney for Applicant
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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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<p>Substitute for Form 1A, NGB/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				<p>Complete if Known</p> <table border="1"> <tr> <td>Application Number</td> <td>09/937,840</td> </tr> <tr> <td>Filing Date</td> <td>09/26/2001</td> </tr> <tr> <td>First Named Inventor</td> <td>Patrick Soon-Shiong</td> </tr> <tr> <td>Group Art Unit</td> <td>1614</td> </tr> <tr> <td>Examiner Name</td> <td>Unknown</td> </tr> <tr> <td>Attorney Docket Number</td> <td>ABI1550-1 (071243-1404)</td> </tr> </table>		Application Number	09/937,840	Filing Date	09/26/2001	First Named Inventor	Patrick Soon-Shiong	Group Art Unit	1614	Examiner Name	Unknown	Attorney Docket Number	ABI1550-1 (071243-1404)
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Examiner Name	Unknown																
Attorney Docket Number	ABI1550-1 (071243-1404)																
Sheet	1	of	4														

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A11	International Search Report for PCT Application No. PCT/US00/10849	
	A12	Supplementary European Search Report for European Patent Application No. EP 00 92 8296.	

Examiner Signature		Date Considered
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INFORMATION DISCLOSURE
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Sheet

2

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Application Number	09/937,840
Filing Date	09/26/2001
First Named Inventor	Patrick Soon-Shiong
Group Art Unit	1614
Examiner Name	Unknown

Attorney Docket Number ABI1550-1 (071243-1404)

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A13	Arbuck et al., "Clinical Development of Taxol." Journal of the National Cancer Institute Monographs No. 15, p. 11-24, 1993.	
	A14	Dorr, "Pharmacology of the Taxanes." Pharmacotherapy, 17:965-1045, 1997.	
	A15	Eisenhauer et al., "European-Canadian randomized trial of Paclitaxel in relapsed ovarian cancer: high-dose versus low-dose and long versus short infusion." Journal of Clinical Oncology, 12:2654-2666, 1994.	
	A16	Fennelly et al., "Phase I and pharmacologic study of Paclitaxel administered weekly in patients with relapsed ovarian cancer." Journal of Clinical Oncology, 15:187-192, 1997.	
	A17	Fletcher et al., "Antinociceptive effect of bupivacaine encapsulated in Poly(D,L)-Lactide-Co-Glycolide microspheres in the acute inflammatory pain model of carrageenin-injected rats." Anesth. Analg., 84:90-94, 1997.	
	A18	Gianni et al., "Nonlinear pharmacokinetics and metabolism of Paclitaxel and its pharmacokinetic/pharmacodynamic relationships in humans." Journal of Clinical Oncology, 13:180-190, 1995.	
	A19	Greco et al., "One-hour Paclitaxel infusions: review of safety and efficacy." The Cancer Journal, 5: 179-191, 1999.	
	A20	Holmes et al., "Final Results: Randomized phase III trial of Paclitaxel by 3-hour versus 96-hour infusion in patients (PT) with MET breast cancer. The long and short of it." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 16:110a, 1998.	
	A21	Holmes et al., "Phase III trial of paclitaxel (P) administered over 3- or 96-hr for metastatic breast cancer (MBC)." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 15:106a, 1996.	
	A22	Hainsworth et al., "Carcinoma of unknown primary site: Treatment with 1-hour Paclitaxel, Carboplatin, and extended-schedule Etoposide." Journal of Clinical Oncology, 15:2385-2393, 1997.	

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Application Number	09/937,840
Filing Date	09/26/2001
First Named Inventor	Patrick Soon-Shiong
Group Art Unit	1614
Examiner Name	Unknown

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	A23	Hainsworth et al., "Paclitaxel administered by a 1-hour infusion: A Phase 1-11 trial comparing two schedules." The Cancer Journal from Scientific American, 1:281-287, 1995.	
	A24	Hainsworth et al., "Paclitaxel by 1-hour infusion: An Active drug in metastatic non-small-cell lung cancer." Journal of Clinical Oncology, 13:1609-1614, 1995.	
	A25	Hainsworth et al., "Paclitaxel, carboplatin, and extended-schedule etoposide in the treatment of small-cell lung cancer: comparison of sequential phase II trials using different dose-intensities." Journal of Clinical Oncology, 15:3464-3470, 1997.	
	A26	Huizing et al., "Pharmacokinetics of Paclitaxel and metabolites in a randomized comparative study in platinum-pretreated ovarian cancer patients." Journal of Clinical Oncology, 11:2127-2135, 1993.	
	A27	Kearns et al., "Paclitaxel pharmacokinetics and pharmacodynamics." Seminars in Oncology, 22:16-23, 1995.	
	A28	Klaassen et al., "Phase I study with a weekly 1 h infusion of paclitaxel in heavily pretreated patients with metastatic breast and ovarian cancer." European Journal of cancer, 32A: 547-549, 1996.	
	A29	Langer et al., "Paclitaxel (P) by 1 or 24 hour (HR) infusion combined with carboplatin © in advanced non-small cell lung carcinoma (NSCLC): a comparative analysis." Meeting abstract. Proceedings of the American Society of Clinical Oncology, 16:45a, 1997.	
	A30	Lopes et al., "Cell kill kinetics and cell cycle effects of taxol on human and hamster ovarian cell lines." Cancer Chemotherapy and Pharmacology, 32:235-242, 1993.	

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Sheet	4	of	4	Application Number	09/937,840
				Filing Date	09/26/2001
				First Named Inventor	Patrick Soon-Shiong
				Group Art Unit	1614
				Examiner Name	Unknown
				Attorney Docket Number	ABI1550-1 (071243-1404)

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	A31	Obtsu et al., "Clinical pharmacokinetics and pharmacodynamics of paclitaxel: A 3-hour infusion versus a 24-hour infusion." Clinical Cancer Research, 1:599-606, 1995.		
	A32	Onetto et al., "Overview of taxol safety." Journal of the National Cancer Institute, Monographs No. 15, p. 131-139, 1993.		
	A33	Seidman et al., "One-hour paclitaxel via weekly infusion: Dose-density with enhanced therapeutic index." Oncology, Vol. 12, No. 1, Supplement No. 1, p. 19-22, 1998.		
	A34	Sonnichsen et al., "Saturable pharmacokinetics and paclitaxel pharmacodynamics in children with solid tumors." Journal of Clinical Oncology, 12: 532-538, 1994.		

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